

**REMARKS**

Reconsideration of the subject application is requested in view of the above amendments and the following remarks.

**I. Claim Status.** Claims 1, 7, and 17 have been amended. Claims 5, 6 and 20-35 are canceled without prejudice or disclaimer.

Claim 1 has been amended to replace the phrase “about 6 to about 45” with “about 6 to 45”. No new matter is added by this amendment.

Claim 7 has been amended to properly depend from claim 1, following cancellation of claim 6 in a prior Amendment. The scope of claim 7 is unchanged.

Claim 17 has been rewritten from a dependent claim to an independent claim, incorporating the elements of the claims from which it previously depended. The scope of claim 17 is unchanged.

By this Amendment, no new matter has been introduced into the application.

Upon entry of this Amendment, claims 1-4 and 7-19 are pending. No new claims have been added to the application. The amendments to claims 1, 7 and 17 do not raise additional issues that need to be searched by the Examiner. Accordingly, the present Amendment should be entered.

**II. Claim Rejections.** The claim rejections set forth in the Final Office Action are summarized and addressed as follows:

*(i) Rejections Under 35 U.S.C. §112, first paragraph (enablement).* Claims 1-4 and 7-19 remain rejected as allegedly failing to be enabled by the specification. The amended claims call for a peptide epitope sequence of about 6 to 45 amino acids in length. The Examiner asserts

that the specification fails to enable one of ordinary skill in the art to make and use the invention when the peptide epitope called for in the claims is less than 10 amino acids in length.

The Examiner's position is that, "The state of the Art [sic] casts doubt on the use of scaffolding for IgG production from allergens and there is evidence in Applicant's specification that an 8-mer did not induce a protective IgG response." The Examiner's position is not well taken.

With respect to the prior art, the Examiner has cited King et al., Ref. 3 on IDS submitted on 10-15-03, (Int. Arch. Allergy Immunol., 2001, 124:85-86) ("King") for the proposition that "hybrid proteins with 20-30 amino acid residues in the peptide epitope sequence have maximal reduction in allergenicity while still retaining adequate immunogenicity." See Office Action dated February 1, 2005 ("Feb. 1 Office Action") at page 3. On its face, however, there is nothing in this statement that suggests that a peptide epitope of 6-10 amino acids would fail to elicit a protective IgG response. There is no requirement that the claimed embodiments of the invention be restricted to "maximal" activity. Moreover, the claims call for the epitope to be present in a surface accessible region of the hybrid protein corresponding to its position in the allergen protein. The surface accessibility further promotes immunogenicity of the peptide epitope.

Additionally, at the time the instant application was filed, it was well known among those of ordinary skill in the art peptide epitopes of six amino acids are effective in eliciting an antibody response. For example, in the context of discussing production of anti-peptide antibodies, Harlow et al., "Antibodies: A Laboratory Manual," 1988, Cold Spring Harbor Laboratories, pp. 72-78 ("Harlow") states that, "The smallest synthetic peptides that will consistently elicit antibodies that bind to the original protein are 6 residues in length." Harlow at page 76, section entitled "Size of Peptide." Hence, by the filing date of the instant application, the general understanding that peptides of 6 amino acids can "consistently" elicit an immune response was so well established that





peptide epitope in a homologous scaffolding) is generally enabled. The state of the art is such that epitopes of 6 amino acids are considered generally immunogenic. The state of the art provides no legitimate reason to suspect that epitopes of 6-9 amino acids would destabilize a protein when it is shown by examples that epitopes of 10 amino acids do not. The level of one of ordinary skill in the art is high. The inventors provide guidance on how to make the hybrid allergens, use them as immunogens, and tests for an IgG response. It is predictable in the art that when used for immunizations, a native protein will illicit an IgG response, to a greater or lesser extent, to epitopes spread across the surface of the protein; and the instant specification reports that at least 4 out of 4 other epitopes of 9-11 amino acids successfully produced an IgG response. Finally, the breadth of the claim sought (a peptide epitope of at least 6 amino acids) is close to the scope of the claim for which the specification provides four working examples (9-11 amino acids). Hence, the great weight of the Wands factors falls in favor of enablement of the full breadth of the present.

For all of the reasons set forth above, the specification enables one of ordinary skill in the art to make and use the full scope of the claimed invention. Withdrawal of the rejection of claims 1-4 and 7-19 for lack of enablement is requested, accordingly.

(ii) Rejections Under 35 U.S.C. §102. Claims 1-4 and 10-17 remain rejected as allegedly anticipated by Monsalve et al., *Allergy Clin. Immunol.* 103(1) Part 2:S181, 1999 (“Monsalve I”) or Monsalve et al., *Arb. Paul Ehrlich Inst.* 93:181-188, 1999 (“Monsalve II”), as evidenced by King et al., *Intl. Arch. Allergy Immunol.* 124:85-86, 2001 (“King et al.”). The Examiner alleges that the art teaches a peptide epitope according to claim 1 of 49 amino acids, upon which the phrase “about 45” reads. In response, without conceding the validity of the rejection, claim 1 has been amended to replace the phrase “about 6 to about 45” with “about 6 to 45”. This



suggest that a grafted epitope sequence should be present in a surface accessible region of a hybrid protein corresponding to its position in the allergen protein, as called for in the claims.

The teachings of Alibhai et al. do not remedy the deficiencies of Monsalve I and II and King et al. Alibhai et al. fails to provide any incentive to shorten the epitopes used in the hybrid proteins of Monsalve I and II below 49 amino acids. For at least this reason, amended claims 1 and 18 are not obvious over the prior art of record. Withdrawal of this rejection is requested.

### CONCLUSION

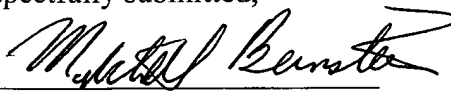
In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By



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